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PPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/997,213	11/27/2001	Tim Kievits	65959/7	4072
75	90 05/19/2004		EXAM	INER
Elie H. Gendloff, Ph.D., Esq.			CHIN, CHRISTOPHER L	
AMSTER, ROT 90 Park Avenue	THSTEIN & EBENSTEIN		ART UNIT	PAPER NUMBER
New York, NY			1641	
			DATE MAILED: 05/19/2004	4

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/997,213	KIEVITS ET AL.
Office Action Summary	Examiner	Art Unit
	Christopher I Chin	1641
The MAII ING DATE of this communication app	pears on the cover sheet with th	e correspondence address
3) Since this application is in condition for allows closed in accordance with the practice under  Disposition of Claims  4) Claim(s) 1-11,18-21 and 31-36 is/are pending 4a) Of the above claim(s) is/are withdred 5) Claim(s) is/are allowed.  6) Claim(s) 1-11,18-21 and 31-36 is/are rejected for the claim(s) is/are objected to.  8) Claim(s) is/are objected to restriction and claim(s) are subject to restriction and application Papers  9) The specification is objected to by the Examination 10) The drawing(s) filed on is/are: a) and applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the c	Pears on the cover sheet with the Y IS SET TO EXPIRE 3 MONT (136(a)). In no event, however, may a reply be only within the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS (e., cause the application to become ABANDO (ing date of this communication, even if timely (ing date of this communication, even if timely (ing date of this communication).  September 2003. It is action is non-final. (increase except for formal matters, Ex parte Quayle, 1935 C.D. 11 (increase of the application). (increase of the application) (i	the Examiner.  See 37 CFR 1.85(a).  Is objected to, See 37 CFR 1.121(d).  Office Action or form PTO-152.
a) ⊠ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority docume  2. ☒ Certified copies of the priority docume  3. ☐ Copies of the certified copies of the priority docume  application from the International Bur	ents have been received. ents have been received in Apportionity documents have been re reau (PCT Rule 17.2(a)).	plication No. <u>09/403,559</u> . eceived in this National Stage
* See the attached detailed Office action for a  Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB Paper No(s)/Mail Date 4/29/02.	4)  Interview Su Paper No(s)	ımmary (PTO-413) /Mail Date formal Patent Application (PTO-152)

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### **DETAILED ACTION**

#### Election/Restrictions

1. Applicant's election without traverse of Group I – claims 1-11, 18-21, and 31-36 has been noted. Applicant is correct indicating that claims 1-11 and 18-21, and 31-36 were the only claims pending and thus the restriction requirement was not necessary.

## Specification

- 2. The disclosure is objected to because of the following informalities:
- a.) The status of 09/843,929 listed on page 1 of the specification should be updated as being issued as U.S. Patent 6,635,493.

Appropriate correction is required.

# Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Claims 1-11, 18-21, and 31-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,225,131. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '131 claims a device and kit with essentially the same limitations as the instantly claimed device and kit.

Patent '131 claims a device for performing an assay comprising a substrate having through-going channels. The channels open out on a surface and oriented essentially perpendicular to the surface for sample application. The channels in at least one area of the surface for sample application being provided with a first binding substance capable of binding to an analyte, wherein the substrate is an electrochemically manufactured metal oxide membrane and the first binding substance is within the through-going channels in the substrate. The first binding substance can be a nucleic acid probe, an antibody, an antigen, a receptor, a hapten, or a ligand for a receptor. The first binding substance is covalently bound to the substrate. The metal oxide membrane can be composed of aluminum oxide. A kit containing the device is also claimed. The kit also includes a detection means for determining the whether binding has occurred between the first binding substance and the analyte. The detection means comprises a second binding substance provided with a label. The label is capable of inducing a color reaction or capable of bio- or chemo- or photoluminescence.

Patent '131 differs from the instant invention in failing to teach a binding substance that is a portion of a HIV protein or HIV genome.

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However, it would have been obvious to one of ordinary skill in the art to use a portion of a HIV protein or HIV genome in the device of patent '131 because the device of patent '131 generically recites using various types of proteins, such as antibodies, antigens, receptors, haptens, and ligands and nucleic acid probes in general. The choice of analyte to be detected in the device of patent '131 dictates the appropriate reagents to be used. Should the analyte to be detected require a portion of a HIV protein or HIV genome then one of ordinary skill in the art would have provided each reagent.

5. Claims 1, 4-6, 8-10, and 31-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,635,493. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '493 claims a method using a device with essentially the same limitations as the instantly claimed device.

### Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher L. Chin Primary Examiner

Christyph L. Chin

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5/17/04